Drugs of Abuse Test Panel

For medical and other professional in vitro diagnostic use only. Cat.No 3032501

INTENDED USE

The Rapid Response Drugs of Abuse Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
AMP (Amphetamine)	Amphetamine	1,000
AMP (Amphetamine)	Amphetamine	300
BAR (Barbiturates)	Secobarbital	300
BZO (Benzodiazepines)	Oxazepam	300
BZO (Benzodiazepines)	Oxazepam	200
BZO (Benzodiazepines)	Oxazepam	100
BUP (Buprenorphine)	Buprenorphine-β-3-D-glucuronide	10
COC (Cocaine)	Benzoylecgonine	300
COC (Cocaine)	Benzoylecgonine	200
COC (Cocaine)	Benzoylecgonine	100
COT (Cotinine)	Cotinine	600
COT (Cotinine)	Cotinine	200
EDDP (Methadone metabolite)	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	100
FYL (Fentanyl)	Fentanyl	10
KET (Ketamine)	Ketamine	1,000
MDA (Methylene-dioxyamphetamine)	Methylenedioxy-amphetamine	500
MDMA (Ecstasy)	3,4-Methylenedioxymeth-amphetamine	1,000
MDMA (Ecstasy)	3,4-Methylenedioxymeth-amphetamine	500
MDMA (Ecstasy)	3,4-Methylenedioxymeth-amphetamine	300
MTD (Methadone)	Methadone	300
MET (Methamphetamine)	Methamphetamine	1,000
MET (Methamphetamine)	Methamphetamine	300
MOP 2000 (Morphine/Heroin)	Morphine	2,000
MOP 300 (Morphine/Heroin)	Morphine	300
MOP 200 (Morphine/Heroin)	Morphine	200
MOP 100 (Morphine/Heroin)	Morphine	100
MQP (Methaqualone)	Methaqualone	300
OXY (Oxycodone)	Oxycodone	100
PCP (Phencyclidine)	Phencyclidine	25
PPX (Propoxyphene)	Norpropoxyphene	300
TCA (Tricyclic antidepressants)	Nortriptyline	1,000
THC (Marijuana)	11-nor-Δ^9-THC-9-COOH	200
THC (Marijuana)	11-nor-Δ^9-THC-9-COOH	150
THC (Marijuana)	11-nor-Δ^9-THC-9-COOH	50
THC (Marijuana)	11-nor-Δ^9-THC-9-COOH	25
TML (Tramadol)	Tramadol	100

PRINCIPLE

The Rapid Response Drugs of Abuse Test Device detects drugs of abuse through visual interpretation of color development on the internal strip. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

- Test devices
- Disposable pipettes
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Positive and negative controls

REAGENTS

Each test consists of a reagent strip mounted in a plastic housing. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components. The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Discard used testing materials in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C (35.6-86 °F) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Rapid Response Drugs of Abuse Test Device is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C (35.6-46.4 °F) for up to 2 days. For long term storage, specimens should be kept below -20°C (-4°F).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C or 59-86°F) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. Take off the cap outside of the test end. With arrows pointing toward the urine specimen, immerse the test panel vertically into the urine specimen for at least 10-15 seconds. Immerse the test panel to at least the level of the wavy lines on the strip(s), do not pass the arrows on the test panel when immersing the panel.
3. Place the test panel on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The results should be read at 5 minutes. Do not interpret results after 10 minutes.

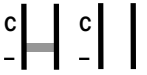
INTERPRETATION OF RESULTS

POSITIVE RESULT:

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Rapid Response Drugs of Abuse Test Device is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of drugs of abuse.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the Rapid Response Drugs of Abuse Test Device was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

Reproducibility

The reproducibility of the Rapid Response Drugs of Abuse Test Device was verified by blind tests performed at four different locations. Samples with drug/metabolite concentrations at 50% of the cut-off were all determined to be negative, while samples with drug/metabolite concentrations at 200% of the cut-off were all determined to be positive.

Precision

Test precision was determined by blind tests with control solutions. Controls with drug/metabolite concentrations at 50% of the cut-off yielded negative results, and controls with drug/metabolite concentrations at 150% of the cut-off yielded positive results.

Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Rapid Response Drugs of Abuse Test Device identified positive results at 5 minutes.

AMP 1000	Concentration (ng/mL)
d-Amphetamine	1,000
l-Amphetamine	>50,000
d-Methamphetamine	>20,000
l-Methamphetamine	>20,000
3,4-Methylendioxyamphetamine (MDA)	2,400
3,4-Methylendioxymethamphetamine (MDMA)	>20,000
3,4-Methylendioxyethylamphetamine (MDEA)	>100,000
Paramethoxyamphetamine (PMA)	1,000
AMP 300	
d-Amphetamine	300
l-Amphetamine	>50,000
3,4-Methylenedioxyamphetamine (MDA)	500
3,4-Methylenedioxymethamphetamine (MDMA)	>20,000
AMP 500	
d-Amphetamine	500
l-Amphetamine	>50,000
3,4-Methylenedioxyamphetamine (MDA)	700
3,4-Methylenedioxymethamphetamine (MDMA)	>20,000
d-Amphetamine	500
l-Amphetamine	>50,000
d-Amphetamine	500
d-Amphetamine	500
l-Amphetamine	>50,000
3,4-Methylenedioxyamphetamine (MDA)	700
3,4-Methylenedioxymethamphetamine (MDMA)	>20,000
BAR 300	
Secobarbital	300
Allobarbital	5,000
Alphenal	625
Amobarbital	600
Aprobarbital	600
Butalbital	3,000
Butabarbital	75
Hexobarbital	>100,000
Pentobarbital	300
Phenobarbital	300
BUP 10	
Buprenorphine	10
Buprenorphine-3-β-d-glucunoride	10
Norbuprenorphine	>1,000
Norbuprenorphine-3-β-d-glucunoride	>1,000
BZO 300	
Oxazepam	300
Alprazolam	125
Bromazepam	500
Chlordiazepoxide	6250
Clobazam	150
Clonazepam	16,000
Clorazepate	4,000
Delorazepam	1,200
Desalkyflurazpam	625
Diazepam	600
Estazolam	4,000
Fentanyl	>100,000
Flunitrazepam	600
Flurazepam	>10,000
α-Hydroxyalprazolam	100,000
Lorazepam	800
Lormetazepam	1,000
Medazepam	>100,000
Midazolam	6,250
Nitrazepam	50,000
Nordiazepam	300
Prazepam	12,500
Temazepam	2,500
Tetrazepam	1,000
BZO 200	
Oxazepam	200
Alprazolam	100
Bromazepam	250
Chlordiazepoxide	6,250
Clobazam	75
Clonazepam	6,000
Clorazepate	3,000
Delorazepam	800
Desalkyflurazepam	313
Diazepam	600
Estazolam	2,000
Fentanyl	>100,000
Flunitrazepam	600
Flurazepam	>1,000
α-Hydroxyalprazolam	12,000
Lorazepam	800
Lormetazepam	250
Medazepam	>100,000
Nitrazepam	25,000
Nordiazepam	156
Prazepam	>100,000
Temazepam	1,250
Triazolam	500
BZO 100	
Oxazepam	100
Alprazolam	90
Bromazepam	250
Chlordiazepoxide	6,250
Clobazam	55
Clonazepam	6,000
Clorazepate	3,000
Delorazepam	600
Desalkyflurazepam	200
Diazepam	600
Estazolam	2,000
Fentanyl	>100,000
Flunitrazepam	600
Flurazepam	>1,000
α-Hydroxyalprazolam	12,000
Lorazepam	800
Lormetazepam	250
Medazepam	>100,000
Midazolam	
Nitrazepam	25,000
Nordiazepam	156
Prazepam	100,000
Temazepam	625
COC 300	
Benzoylecgonine	300
Cocaine	1,000
Ecgonine	>40,000
Ecgonine methyl ester	>100,000
COC 100	
Benzoylecgonine	100
Cocaine	300
Ecgonine	>40,000
Ecgonine methyl ester	>100,000
COC 200	
Benzoylecgonine	200
Cocaine	800
Ecgonine	>40,000
Ecgonine methyl ester	>100,000
COT 200	
Cotinine	200
(-)-Nicotine	>50,000
COT 600	
Cotinine	600
(-)-Nicotine	>50,000
EDDP 100	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	100
Doxylamine	>1,000,000
Methadol	>10,000
Methadone	>10,000
FYL 10	
Fentanyl metabolites	10
KET 1000	
Ketamine	1,000
d-Amphetamine	>100,000
Dextromethorphane	1,000
Lidocaine	>100,000
Methadol	50,000
Methadone	25,000
Methampetamine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	>100,000
Norketamine	2,000
Pethidine	12,500
Phencyclidine	>10,000
Promethazine	20,000
MDA 500	
(±)-3,4-Methylenedioxyamphetamine	500
3,4-Methylenedioxyethylamphetamine	300
MDMA 1000	
3,4-Methylenedioxymeth-amphetamine (MDMA)	1,000
d-Amphetamine	>100,000
d-Methamphetamine	100,000
l-Methamphetamine	>100,000
3,4-Methylenedioxy-amphetamine (MDA)	2,000
3,4-Methylenedioxyethyl-amphetamine (MDEA)	600
MDMA 500	
3,4-Methylenedioxymeth-amphetamine (MDMA)	500
d-Amphetamine	>100,000
d-Methamphetamine	>100,000
3,4-Methylenedioxy-amphetamine (MDA)	1,000
3,4-Methylenedioxyethyl-amphetamine (MDEA)	300
Paramethoxyamphetamine (PMA)	5,000
MDMA 300	
(±)-3,4-Methylenedioxymeth-amphetamine (MDMA)	300
d-Amphetamine	>100,000
d-Methamphetamine	>100,000
(±)-3,4-Methylenedioxy-amphetamine (MDA)	600
(±)-3,4-Methylenedioxyethyl-amphetamine (MDEA)	180
Paramethoxyamphetamine (PMA)	5,000
MTD 300	
Methadone	300
Doxylamine	>40,000
2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP)	>40,000
Methadol	1,000
MET 1000	
d-Methamphetamine	1,000
d-Amphetamine	>40,000
Chloroquine	10,000
(±)-Ephedrine	>100,000
l-Methamphetamine	15,000
3,4-Methylenedioxy-amphetamine (MDA)	>10,000
3,4-Methylenedioxymeth-amphetamine (MDMA)	2,000
3,4-Methylenedioxyethyl-amphetamine (MDEA)	20,000
Procaine	100,000
MET 300	
(+)-Methamphetamine	300
d-Amphetamine	>40,000
Chloroquine	5,000
(±)-Ephedrine	>100,000
l-(-)-Methamphetamine	10,000
Mephentermine	50,000
(±)-3,4-Methylenedioxymeth-amphetamine (MDMA)	1,000
(±)-3,4-Methylenedioxyethyl-amphetamine (MDEA)	10,000
β-Phenylethylamine	35,000
Procaine	35,000
Ranitidine	35,000
MET 500	
(+)-Methamphetamine	500
d-Amphetamine	>40,000
Chloroquine	8,000
(±)-Ephedrine	>100,000
Mephentermine	50,000
l-Methamphetamine	12,000
(±)-3,4-Methylenedioxymeth-amphetamine (MDMA)	1,200
(±)-3,4-Methylenedioxyethyl-amphetamine (MDEA)	12,000
β-Phenylethylamine	50,000
Procaine	50,000
Ranitidine	50,000
MOP 2000	
Morphine	2,000
Codeine	2,000
Diacetylmorphine (Heroin)	2,000
Ethylmorphine	600
Hydromorphone	15,000
Hydrocodone	15,000
Merperidine	>100,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine-3-β-d-glucuronide	10,000
Oxycodone	>20,000
Oxymorphone	>20,000
Rifampicine	>50,000
Thebaine	20,000
MOP 300	
Morphine	300
Codeine	300
Diacetylmorphine (Heroin)	300
Ethylmorphine	300
Hydromorphone	1,500
Hydrocodone	1,500
Merperidine	>100,000
6-Monoacetylmorphine (6-MAM)	300
Morphine-3-β-d-glucuronide	6,000
Oxycodone	>20,000
Oxymorphone	>20,000
Promethazine	>250,000
Rifampicine	25,000
Thebaine	2,50
Trimipramine	>20,000
MOP 100	
Morphine	100
Codeine	100
Diacetylmorphine (Heroin)	100
Ethylmorphine	100
Hydromorphone	500
Hydrocodone	500
Meperidine	>100,000
6-Monoacetylmorphine (6-MAM)	100
Morphine-3-β-d-glucuronide	2,000
Oxycodone	>20,000
Oxymorphone	>20,000
Promethazine	>250,000
Rifampicine	8,400
Thebaine	8,400
Trimipramine	>20,000
MOP 200	
Morphine	200
Codeine	200
Diacetylmorphine (Heroin)	200
Ethylmorphine	200
Hydromorphone	1,000
Hydrocodone	1,000
Meperidine	>100.000
6-Monoacetylmorphine (6-MAM)	200
Morphine-3-β-d-glucuronide	4,000
Oxycodone	>20,000
Oxymorphone	>20,000
Promethazine	>250,000
Rifampicine	16,600
Thebaine	1,700
Trimipramine	>20,000
MQL 300	
Methaqualone	300
Amitriptyline	50,000
Carbamazepine	20,000
2′-Hydroxy methaqualone	3,000
3′-Hydroxy-methaqualone	500
4′-Hydroxy-methaqualone	500
Mecloqualone	500
Nortriptyline	50,000
Phenytoin	40,000
Primidone	24,000
Theophylline	40,000
OXY 100	
Oxycodone	100
Codeine	>100,000
Diacetylmorphine (Heroin)	>100,000
Ethylmorphine	10,000
Hydrocodone	10,000
Hydromorphone	10,000
Meperidine	>100,000
6-Monoacetylmorphine (6-MAM)	>100,000
Morphine	>250,000
Morphine-3- β -d-glucuronide	>100,000
Oxymorphone	500
Thebaine	>100,000
PCP 25	
Phencyclidine	25
Thienylcyclohexylpiperidine (TCP)	3,000
PPX 300	
d-Propoxyphene	300
d-Norpropoxyphene	300
TCA 1000	
Nortriptyline	1,000
Amitriptyline	1,000
Chlorpromazine	3,500
Clomipramine	10,000
Cyclobenzaprine	1,500
Desipramine	500
Diphenyldramine	20,000
Doxepine	1,000
Imipramine	800
Nordoxepine	1,000
Opipramol	4,000
Protriptyline	3,000
Doxepine	1,000
Perphenazine	25,000
Promazine	200
Promethazin	40,000
Protryptyline	3,000
Trimipramine	2,500
THC 50	
11-nor-Δ^8-THC-9-COOH	50
Cannabinol	20,000
Cannabidiol	>100,000
11-hydroxy-Δ^9-Tetrahydrocannabinol	>100,000
11-nor-Δ^9-THC-9-COOH	50
Δ^8- Tetrahydrocannabinol	15,000
Δ^9- Tetrahydrocannabinol	15,000
THC 25	
11-nor-Δ^9-THC-9-COOH	25
Cannabinol	15,000
Cannabidiol	>100,000
11-Hydroxy-Δ^9-tetrahydrocannabinol	>100,000
11-nor-Δ^8-THC-9-COOH	25
Δ^8-Tetrahydrocannabinol	10,000
Δ^9-Tetrahydrocannabinol	10,000
THC 150	
11-nor-Δ^8-THC-9-COOH	150
Cannabinol	>20,000
Cannabidiol	>100,000
11-Hydroxy-Δ^9-tetrahydrocannabinol	>100,000
11-nor-Δ^9-THC-9-COOH	150
Δ^8-Tetrahydrocannabinol	80,000
Δ^9-Tetrahydrocannabinol	80,000
THC 200	
11-nor-Δ^8-THC-9-COOH	200
11-nor-Δ^9-THC-9-COOH	200
11-Hydroxy-Δ^9-tetrahydrocannabinol	>100,000
Δ^8-Tetrahydrocannabinol	>80,000
Δ^9-Tetrahydrocannabinol	>80,000
Cannabinol	>20,000
Cannabidiol	>100,000
TML 300	
11-nor-Δ^8-THC-9-COOH	200
11-nor-Δ^9-THC-9-COOH	200
11-Hydroxy-Δ^9-tetrahydrocannabinol	>100,000

The following compounds yielded negative results up to a concentration of 100 µg/mL:

Acetaminophen	Ethanol
Acetone	Furosemide
Acetylsalicylic acid	Guaiacol glyceryl ether
Albumin	Hemoglobin
Ampicillin	Ibuprofen
l-Ascorbate	(±)-Isoproterenol
Aspartame	N-Methyl-ephedrine
Atropine	(+)-Naproxen
Benzocaine	Oxalic acid
Bilirubin	Penicillin-G
Caffeine	Pheniramine
Chlorpheniramine	Phenothiazine
Creatine	L-Phenylephrine
Dextrorphan tartrate	β-Phenylethylamine
4-Dimethylaminoantipyrine	Quinidine
Dopamine	Sulindac
Erythromycin	Tyramine

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